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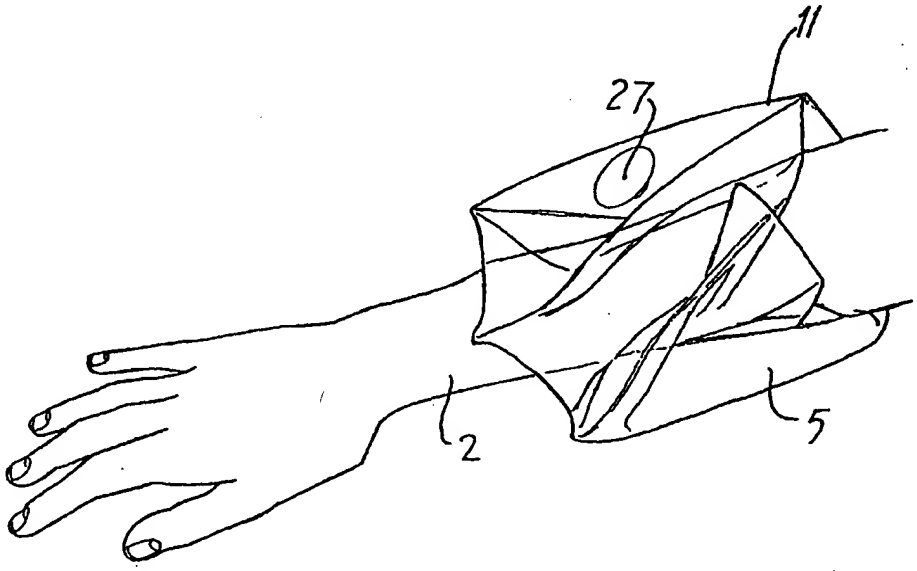

(57) Abstract

An exsanguinator (1) for exsanguinating a limb such as an arm (2) comprises a substantially tubular sleeve (5) which is turned axially back on itself and twisted to define an outer sleeve section (11) and an inner twisted sleeve section (12). The inner sleeve section (12) defines a lumen (25) of reduced cross section which sealingly engages a limb. As the sleeve (5) is passed up along a limb it is inflated to an exsanguinating pressure. When the sleeve (5) has reached the top of the limb a tourniquer pressure is applied.

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"AN EXSANGUINATOR"

The present invention relates to an exsanguinator for exsanguinating limbs to create a bloodless field in advance of certain orthopaedic procedures and to maintain the area of interest ischaemic or blood-free during such procedures.

Certain orthopaedic procedures require a bloodless field of operation for the surgery to be performed easily. The presence of blood in the operative field can obscure the view of the surgeon and act as a hindrance to the speedy execution of the procedure. To overcome this problem a process of exsanguination is applied to the limb. To prevent blood from re-entering the limb a tourniquet is applied to the proximal part of the limb following exsanguination.

At present exsanguination is achieved by three commonly applied methods. In one case a limb is elevated for a short period and by gravity and blood empties from the limb. Removal of blood may be assisted by massaging the limb towards the heart or compressing it with the hands. This method is effective to remove venous blood from the limb but does not prevent arterial blood from re-entering the limb as the high pressures in arteries can overcome the effect of gravity. A pressure cuff or tourniquet may be applied at the top of the limb after a suitable period of time.

Another method is to apply elasticated bandages to the limb starting at the most distal part and working back towards the heart. The bandages are usually made of rubber and are one to three mm thick and approximately 10 centimetres wide. The bandage is applied by stretching it before each wrapping and overlapping the previous wrapping. When the top of the limb has been reached a pressure cuff or tourniquet may be applied to maintain ischaemia. This method is more effective than simple elevation of the limb, however it is time consuming and requires

operator skill. In addition, this method cannot be used safely on fractured limbs due to the lateral forces applied in stretching the bandage.

US-A-4228792 describes an exsanguinator comprising a double-walled tubular sleeve of elastomeric material. The tubular sleeve is rolled up the limb towards the heart. The pressure inside the device is such that it causes emptying of the venous system in the limb. A tourniquet or pressure cuff may be applied when the device has reached the top of the limb. This exsanguinator is however relatively difficult to operate and is relatively inefficient in exsanguinating a limb.

In all cases it is necessary to apply a tourniquet or pressure cuff to the limb to prevent blood from re-entering the limb. The pressure in these cuffs must be sufficiently high to occlude all arterial flow. It is often necessary to inflate these cuffs to a pressure greater than 300mmHg in the case of arms and up to 500mmHg in the case of legs. Significant damage to underlying structures such as nerves and blood vessels has been reported as a result of pressure cuffs. Underlying skin can be damaged due to the shear stress of the pressure cuff. To minimise these problems woollen bandages are often applied to the limb beneath the pressure cuff in an effort to reduce trauma to underlying structures.

When the limb has been made ischaemic a prepping solution is applied. This is a liquid normally containing chlorohexidrine, iodine or a similar bactericide that is painted onto the limb in advance of surgery. These liquids are known to cause severe chemical skin burns if they seep under the woollen bandages or are allowed to pool in an area already under shear stress from the pressure cuff.

There is a need for an exsanguinator which will overcome at least some of these problems.

Summary of the Invention

According to the invention there is provided an exsanguinator for exsanguination of a limb comprising:

a sleeve having an outer sleeve section and a twisted inner sleeve section;

a chamber for pressurised fluid defined between the inner and outer sleeve sections;

the twisted inner sleeve section defining a reduced lumen section to receive a limb; and

the sleeve being evertable so that as the sleeve is passed over a limb a twisted inner sleeve section is rolled over outwardly to become an outer sleeve section and an outer sleeve section is correspondingly rolled over inwardly to become a twisted inner sleeve section.

In a preferred embodiment the sleeve is turned axially back on itself to define the sleeve sections.

Preferably the sleeve is of pliable material.

In a preferred embodiment the outer sleeve section is a substantially cylindrical sleeve section and the inner sleeve section is a twisted sleeve section of the same untwisted diameter as that of the outer sleeve section.

Ideally the chamber is fluid impermeable.

Preferably the chamber is inflatable. In this case the chamber has a port for inflation of the chamber.

In a preferred embodiment of the invention the exsanguinator includes an anti-roll-off means.

The anti-roll-off means may be formed by a stocking over which the sleeve is rolled and retaining means for retaining the sleeve folded over the sleeve. Typically, the retaining means is a releasable fastening means.

In a preferred embodiment the exsanguinator includes a fluid barrier between a proximal end of a limb and the sleeve.

The fluid barrier preferably comprises a seal through which a limb is passed. The seal may be a lip-type seal.

In one embodiment the fluid barrier is mounted or mountable to a cover for the exsanguinator sleeve. Preferably the cover is open at a distal end for engaging over the exsanguinator sleeve.

Preferably the exsanguinator includes retaining means for fastening the cover to a limb. The retaining means is preferably a releasable fastening means.

In another aspect the invention provides a method for exsanguinating a limb comprising the steps of:

placing an evertable sleeve over a limb;

pressurising the evertable sleeve to an exsanguinating pressure;

everting the sleeve over the limb so that as the sleeve is passed over the limb an inner sleeve section is rolled over outwardly to become an outer

sleeve section and an outer sleeve section is correspondingly rolled over inwardly to become an inner sleeve section; and

after exsanguinating the limb, applying a pressure to the sleeve to substantially prevent the flow of blood in the limb.

Preferably the sleeve is pressurised to about 50 to about 70 mm Hg for exsanguination of the limb. The exsanguination pressure may be approximately 60 mm Hg.

In a preferred embodiment the sleeve is pressurised to at least 250 mm Hg to substantially prevent the flow of blood in the limb.

In one embodiment the method includes the step of applying a fluid barrier between the sleeve and the limb.

Most preferably the method includes the step of fixing the sleeve in a desired position on a limb.

In a preferred method of the invention the exsanguinator is an exsanguinator of the invention.

Brief Description of the Drawings

The invention will be more clearly understood from the following description thereof given by way of example only in which:-

Fig. 1 is a perspective view of an exsanguinator according to the invention;

Fig. 2 is a longitudinal cross sectional view of the exsanguinator of Fig. 1;

Fig. 3 is an end view of the exsanguinator;

Fig. 4 is a perspective view of the exsanguinator, in use;

Fig. 5 is another perspective view of the exsanguinator, in use;

Fig. 6 is a cross sectional view of the exsanguinator of Fig. 5 showing a patients limb;

Fig. 7(a) to 7(f) illustrate various steps in a method of exsanguinating a limb;

Fig. 8 is a perspective view of portion of another exsanguinator;

Fig. 9 is perspective view of an exsanguinator cover in use;

Figs. 10 and 11 are views illustrating the cover of Figs. 8 and 9 in use;

Fig. 12 is a perspective view of a tube from which the device may be formed;

Fig. 13 is a view of the tube of Fig. 12 partially folded over;

Fig. 14 is a view of the sleeve of Fig. 13 in a twisted configuration;

Fig. 15 is a side view of the twisted sleeve;

Figs. 16 and 17 are respectively plan and elevational views of a non-twisted sleeve;

Figs. 18 and 19 are respectively plan and elevational views of a twisted sleeve;

Figs. 20 and 21 are respectively plan and elevational views of the twisted sleeve with an object extending through the lumen of the sleeve;

Figs. 22 to 27 are views of the twisting of a tube similar to Figs. 11 to 21;

Figs. 28 and 29 are a graphical representation of the angle of twist plotted against lumen diameter.

Fig. 30 is a perspective view of a twisted tube with an elongate object passing therethrough;

Fig. 31 is an end view of the tube of Fig. 32;

Figs. 33 to 38 are various plan and elevational views illustrating the formation and internal pressurising of a thin walled tube;

Figs. 39 to 49 are various plan and elevational views illustrating the formation and internal pressurising of a thin walled twisted tube; and

Figs. 50 to 55 are various side cross sectional and end views illustrating the translation of a elongate object through a twisted tube.

Detailed Description

Referring to the drawings and initially to Figs. 1 to 7 there is illustrated an exsanguinator 1 for use in a limb such as an arm 2.

Referring in particular to Figs. 12 to 15 the exsanguinator comprises a substantially tubular sleeve 5 of pliable gas tight material formed in from a tube 10 of a suitable biocompatible plastics material. The tube 10 is turned axially back on itself to define an outer sleeve section 11 and an inner sleeve section 12. The tube 10 is twisted so that the axially opposite datum indicators 15, 16 are circumferentially spaced-apart as illustrated in Fig. 14.

The inner and outer sleeve sections 11, 12 define therebetween a sealed inflatable chamber 20. The inner sleeve section 12, defines a lumen 25 and, on inflation of the chamber 20, the inner sleeve section 12 sealingly engages a limb 2 extending through the lumen 25.

The sleeve 5 includes a port 27 fitted with a valve for connection to a suitable inflation means.

In use, an anti-roll off means in the form of a stocking 30 is applied to the limb.

The device 1 is applied by first inflating to an exsanguinating pressure of about 50 to 70 mm Hg, typically approx. 60 mm Hg. The device is then rolled onto the limb 2 to be exsanguinated towards the heart. The device 1 is readily rolled up the limb 2 and as it is pressurised it creates a rolling pressure front, which is greater than mean systolic pressure in the limb 2, as it moves up the limb 2. This causes the displacement of venous blood from the limb 2 and prevents reperfusion through the arterial system. When the device has reached the top of the limb 2 causing it to be exsanguinated it is further inflated to achieve a tourniquet effect thus preventing the re-entry of blood into the limb 2.

The device can be attached to readily available pressure regulation equipment found in operating theatres. The simple construction method of the device allows it to be manufactured in a variety of sizes that can be selected for use with limbs of different size and thickness. In this manner the device will apply an appropriate

amount of pressure, when it is in the tourniquet mode of operation, and so minimise the likelihood of causing damage to underlying structures. The device is easy to inflate and deploy onto the limb 2 to be exsanguinated.

When the exsanguinator sleeve 5 has exsanguinated the limb 5 an anti-roll off means and/or an eversion limiting means is applied to maintain the exsanguinator 1 in position. In this case the anti-roll off means is provided by part 31 of the stocking 30 which is folded back over the exsanguinator sleeve 5 and the free end of the stocking is retained in place using a suitable releasable fastening means such as strips 33 of releasable fabric available under the trade mark Velcro.

Referring to Figs. 8 to 11 there is illustrated a cover 40 for the exsanguinator device 1. The cover 40 is open at one end 41 and a drawstring 42 or other suitable releasable fastening means is used to fix the cover in position on a limb 2. A fluid barrier in the form of a disc 45 of elastomeric material with a central limb-receiving lumen 46 is attached to the cover 40. The cover 40 is of elasticated, permeable or impermeable material with the drawstring 42 at one end and the polymeric or silastic lip-seal 45 at the other end. The hole 46 in the seal 45 is smaller than the diameter of the limb 2 around which it is to seal. The cover 40 is pulled up the limb 2 in the direction of venous flow after the exsanguinator 1 has been positioned and further inflated for its tourniquet effect. The drawstring end precedes the lip-seal end when pulling the cover 40 up the limb 2. The cover 40 is placed over the exsanguinator 1 and the drawstrings 42 pulled. The cover 42 prevents the exsanguinator 1 from rolling back down the limb 2. The lip-seal 45 prevents the passage of bactericidal limb preparation fluid underneath the exsanguinator.

The exsanguinator 1 may be used both as a means of exsanguinating a limb and as a means of maintaining the limb 2 ischaemic. The twisted sleeve provides an even distribution of pressure over and a limb 2 being exsanguinated. In addition, because the sleeve 5 is twisted it is more easily moved along a limb 2 than a non-

twisted sleeve. The exsanguinator 1 includes means for protecting the skin under the device from damage caused by pooling of bactericidal liquid. The exsanguinator may be readily sterilised and therefore used following the sterilisation and prepping of the limb to be exsanguinated without contaminating the sterile field.

The principles which underlie this invention will be clearer from the following description with reference to Figs. 16 to 55.

Fig. 16 depicts a thin walled tube of pliable material. It can be considered as a number of longitudinal elements, typical of which is the element A-B. Clearly there is a lumen passing through the tube, the diameter of which is the diameter of the tube. Rotation of one end of the tube relative to the other end about the axis of the tube causes the tube to twist into the configuration shown in Fig. 18.

The element A-B is now inclined to the axis of the tube but still remains a straight element. It is clear that element A-B in Fig. 18 appears longer than element A-B in 16 (it must have stretched). It follows therefore, that a force must be applied to the element to cause this elongation. In the absence of such a force elongation of the element A-B would not occur and the overall length of the tube would reduce (not depicted) in order to accommodate the change in geometry. At angles of twist less than 180° the element will not intersect the axis of the tube, its mid point being the point of closest proximity to the axis. It is the summation of all the elements at their midpoints that defines the minimum diameter of the reduced lumen formed. This diameter can be calculated knowing the original tube diameter and the angle of twist. The profile of the tube takes the form of a waisted, necked or hourglass shape. This profile is not determined by the shape of any individual element or elements but is the effect of a section in the plane of the tube axis taken through all the elements. Before proceeding to the effects of the introduction of an object into the reduced lumen particular notice should be taken

of the elements as they appear in the plan view Fig. 17. All the elements are straight.

Clearly, if an object of smaller diameter than the reduced lumen were introduced into the reduced lumen the object could pass through with out making contact with the wall of the reduced lumen. It would therefore not be possible for the tube to grip or create a seal to the object. In order to accommodate the introduction of an object of larger size (diameter) it is necessary that each element deform or bend outward thus forming an increased lumen. This can be seen clearly in Fig. 20. All the elements are now deformed. As before there is an apparent increase in the length of the elements. Also as before, in the absence of a force to elongate the elements the overall length of the tube will reduce to accommodate the change in geometry (not depicted). So it will be understood that the lumen has increased to accommodate the introduced object with out stretching the material of the tube and that the tube is intimate contact with the introduced object over at least part of its length.

The application of an axial force to the tube will cause the now deformed elements to try to straighten. Because the elements of the tube do not lie in the plane of the applied axial force there will be a corresponding radially inward force. This tendency toward straightening of the elements will be restricted by the presence of an object in the lumen. Therefore the radially inward component of the applied force will act on the inserted object creating a pressure or gripping force between the tube and the inserted object.

Referring to Figs. 22 to 27 consider the hollow cylindrical tube shown in Fig. 23. The wall of the cylinder defines a lumen through its centre. Consider a linear element A-B. If the upper edge of the tube is rotated through some angle, point A will move to the position shown in Figs. 24 and 25. The element A-B will still define a straight line. The tube will distort into a nominally hour glass shape with

a reduced lumen at mid height. The diameter of the lumen at the neck of the tube is dependant on the angle of twist. When the upper edge is rotated through 180° the lumen will close down to zero diameter. At any horizontal plane through a twisted tube the material must be wrinkled and hence under compressive hoop stress. If the height of the tube remains unaltered then the element A-B in a twisted tube, being larger than in a plain tube, must be under tensile stress. If the tube is free of axial constraint the overall length of the tube will reduce.

Angle of twist Vs. lumen diameter

Fig. 29 shows the lumen diameter (D2) as a proportion of the tube diameter (D1) for angles of twist (E) from 0° to 180°. The lumen diameter (D2) is calculated from:

$$D2 = D1 \cos(E/2).$$

As can be seen, the lumen diameter is independent of the tube length.

Elongate object passed through twisted tube

As can be seen from Figs. 29, 30 and 31 the angle of twist necessary to collapse the lumen of a tube to the diameter of an elongate object passed therethrough is dependant on the ratio of the tube diameter to the diameter of the elongate object. The angle of twist can be calculated from:

$$E = 2\{\cos^{-1}(D2/D1)\}$$

where E is the angle of twist,

D1 is the tube diameter, and

D2 is the diameter of the elongate object.

Although depicted as of circular profile, a tube of sufficiently compliant material will conform to many non recursive profiles. For such a profile D2 is taken as the smallest diameter which can be inscribed within the profile.

Twin walled pressure vessel under internal pressure

Referring to Figs. 32 to 38 consider a thin walled tube as shown in Fig. 33. One end of the tube is folded back on itself as shown in Fig. 35 and the free ends conjoined. What is defined is essentially a twin walled tube (or two coaxial tubes conjoined at their ends) with an enclosed volume between the two walls. One way of extending the thin walled tube in an axial direction is to introduce a pressurised fluid into the enclosed volume. This causes the outer tube to be subject to tensile axial stress and tensile hoop stress. The inner tube will be subject to tensile axial stress and compressive hoop stress. As a result the diameter of the lumen reduces and the lumen collapses into a nominally duck bill configuration but constrained by the outer tube, Fig. 38.

Greater control of the lumen can be obtained by the introduction of a twist into the tube. The tube shown in Fig. 40 is twisted as shown in Fig. 42. One end of the tube is folded back on itself, as shown in Fig. 44, and the free ends conjoined. This configuration defines two coaxial conical vessels conjoined at their bases and at a common apex. However the common apex is not constrained to remain in this configuration. In reality, the inner and outer tubes are free to behave as individual tubes each with half of the original twist and as such the composite tube can better be defined as two coaxial hour glass tubes as shown in Fig. 59, each containing half the original total twist. As both the inner and outer tubes are necked they each are subject to compressive hoop stresses.

Next a pressurised fluid is introduced into the enclosed volume. The introduction of the pressurised fluid extends the inner and outer tubes in an axial direction,

reducing the lumen diameter. The outer tube is a necked hour glass tube with compressive hoop stresses. The introduction of the pressurised fluid also induces tensile hoop stresses, negating the compressive hoop stresses induced by the twist. Since, to remain in its twisted configuration, the tube must have compressive hoop stresses and since the pressurised fluid overcomes these compressive stresses the tube untwists and takes on a nominally cylindrical configuration, Fig. 39. Since the inner and outer tubes are conjoined, as the outer tube untwists the inner tube twists more in response. Since the outer tube now has no twist the inner tube must have all the twist. If the original total twist were 180° then the lumen would close totally. Additionally, the material defining the inner tube will be central within the diameter of the outer tube. This configuration will for brevity be called a Cyclops.

Translation of an elongate object through a Cyclops

Consider the arrangement depicted in Fig. 50. A shaft is passed through a Cyclops with the lumen in mutual contact with the shaft. The outer tube of the Cyclops is resting in mutual contact with a fixed surface. Consider points of contact A, between the Cyclops and the fixed surface, and B, between the shaft and the lumen of the Cyclops. As the shaft is translated, as shown in Fig. 52, point A remains fixed whilst the leading end of the lumen rolls out. Since the Cyclops does not change in overall length the trailing end of the outer tube rolls in as depicted. It will be apparent that the shaft translates to the right twice as far as the Cyclops. This is exactly the motion of a caterpillar tract. From this point of view a Cyclops could be considered as a three dimensional caterpillar tract. Since points A and B on the Cyclops do not move relative to their corresponding positions on the shaft and the fixed surface there is no frictional resistance to the translation of the shaft. In Fig. 54, the Cyclops has translated to the right by approximately its own length. The material which had originally formed the inner tube has rolled out to become the outer tube and vice versa. In other words

the Cyclops has turned inside out. Since the inner tube of the Cyclops is in a twisted configuration and since the point B remains in contact with the same point, the shaft rotates about it's axis as depicted by arrow C (in this instance approx. 120°). In order to obtain this translation the resistance required to be overcome is that generated as the leading and trailing ends of the Cyclops deform as they roll out and roll in respectively.

Reference is also made to appropriate alternatives and modifications which are outlined in our parallel applications referenced ATRO1/C, ATRO12/C, ATRO14/C/, ATRO16/C/, ATRO17/C, the entire contents of which are incorporated herein by reference.

The invention is not limited to the embodiments hereinbefore described which may be varied in construction and detail.

Claims

1. An exsanguinator for exsanguination of a limb comprising:

a sleeve having an outer sleeve section and a twisted inner sleeve section;

a chamber for pressurised fluid defined between the inner and outer sleeve sections;

the twisted inner sleeve section defining a reduced lumen section to receive a limb; and

the sleeve being evertable so that as the sleeve is passed over a limb a twisted inner sleeve section is rolled over outwardly to become an outer sleeve section and an outer sleeve section is correspondingly rolled over inwardly to become a twisted inner sleeve section.

2. An exsanguinator as claimed in claim 1 wherein the sleeve is turned axially back on itself to define the sleeve sections.

3. An exsanguinator as claimed in claim 1 or 2 wherein the sleeve is of pliable material.

4. An exsanguinator as claimed in any preceding claim wherein the outer sleeve section is a substantially cylindrical sleeve section and the inner sleeve section is a twisted sleeve section of the same untwisted diameter as that of the outer sleeve section.

5. An exsanguinator as claimed in any preceding claim wherein the chamber is fluid impermeable.

6. An exsanguinator as claimed in any preceding claim wherein the chamber is inflatable.

7. An exsanguinator as claimed in any preceding claim wherein the chamber has a port for inflation of the chamber.

8. An exsanguinator as claimed in any preceding claim including an anti-roll-off means.

9. An exsanguinator as claimed in claim 8 wherein the anti-roll-off means is formed by a stocking over which the sleeve is rolled and retaining means for retaining the sleeve folded over the sleeve.

10. An exsanguinator as claimed in claim 9 wherein the retaining means is a releasable fastening means.

11. An exsanguinator as claimed in any preceding claim including a fluid barrier between a limb and the sleeve.

12. An exsanguinator as claimed in claim 11 wherein the fluid barrier comprises a seal through which a limb is passed.

13. An exsanguinator as claimed in claim 12 wherein the seal is a lip-type seal.

14. An exsanguinator as claimed in any of claims 11 to 13 wherein the fluid barrier is mounted or mountable to a cover for the exsanguinator sleeve.

15. An exsanguinator as claimed in claim 14 wherein the cover is open at a distal end for engaging over the exsanguinator sleeve.

16. An exsanguinator as claimed in claim 14 or 15 including retaining means for fastening the cover to a limb.

17. An exsanguinator as claimed in claim 16 wherein the retaining means is a releasable fastening means.

18. An exsanguinator substantially as hereinbefore described with reference to the accompanying drawings.

19. A method for exsanguinating a limb comprising the steps of:

placing an evertable sleeve over a limb;

pressurising the evertable sleeve to an exsanguinating pressure;

everting the sleeve over the limb so that as the sleeve is passed over the limb an inner sleeve section is rolled over outwardly to become an outer sleeve section and an outer sleeve section is correspondingly rolled over inwardly to become an inner sleeve section; and

after exsanguinating the limb, applying a pressure to the sleeve to substantially prevent the flow of blood in the limb.

20. A method as claimed in claim 19 wherein the sleeve is pressurised to about 50 to about 70 mm Hg for exsanguination of the limb.

21. A method as claimed in claim 20 wherein the exsanguination pressure is approximately 60 mm Hg.

22. A method as claimed in any of claims 19 to 21 wherein the sleeve is pressurised to at least 250 mm Hg to substantially prevent the flow of blood in the limb.

23. A method as claimed in any of claims 19 to 22 including the step of applying a fluid barrier between the sleeve and the limb.

24. A method as claimed in any of claims 19 to 23 including the step of fixing the sleeve in a desired position on a limb.

25. A method as claimed in any of claims 19 to 24 wherein the exsanguinator is an exsanguinator as claimed in any of claims 1 to 18.

26. A method for exsanguinating a limb substantially as hereinbefore described with a reference to the accompanying drawings.

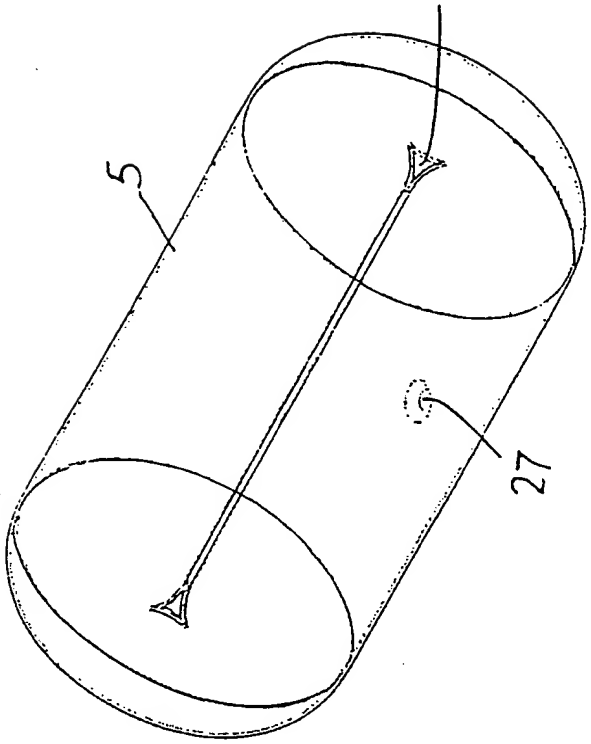

Fig.1

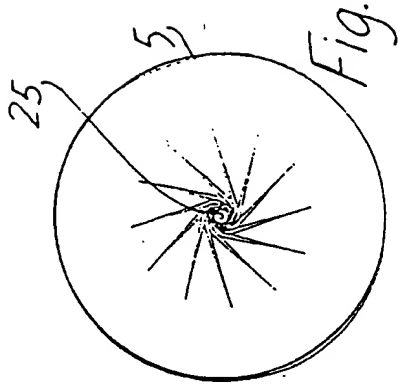

Fig.3

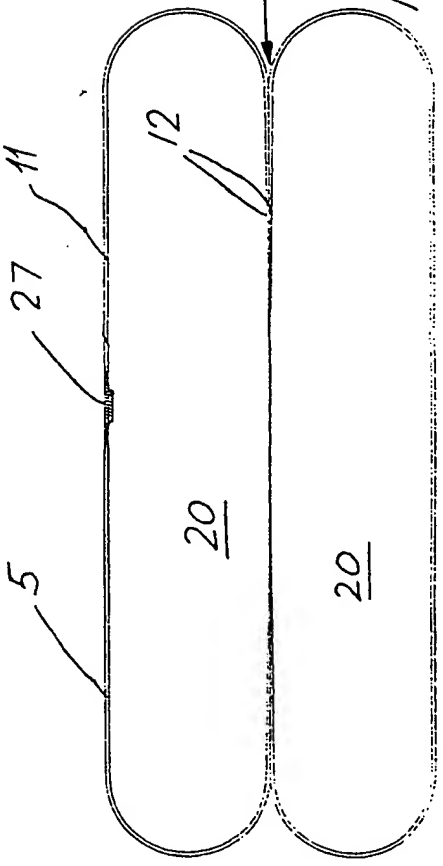

Fig.2

Fig. 4

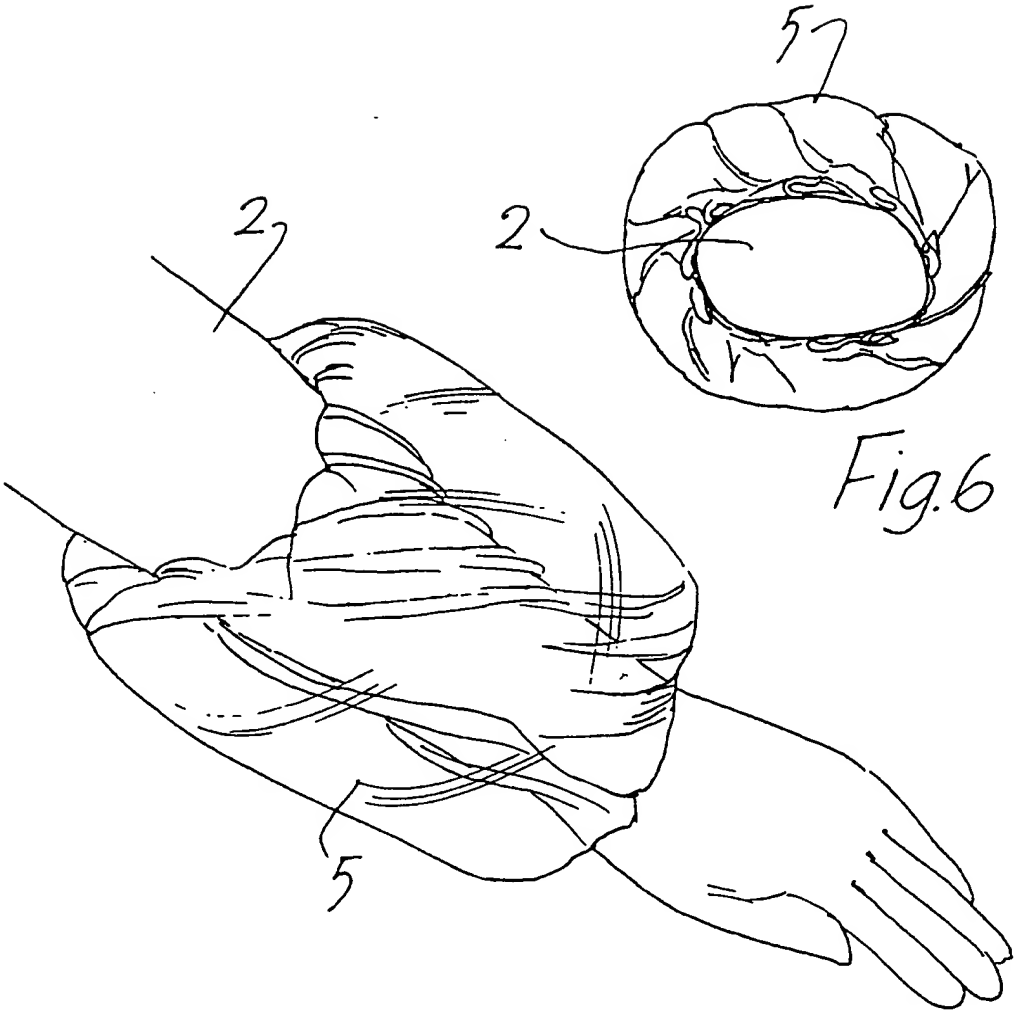

Fig.6

Fig. 5

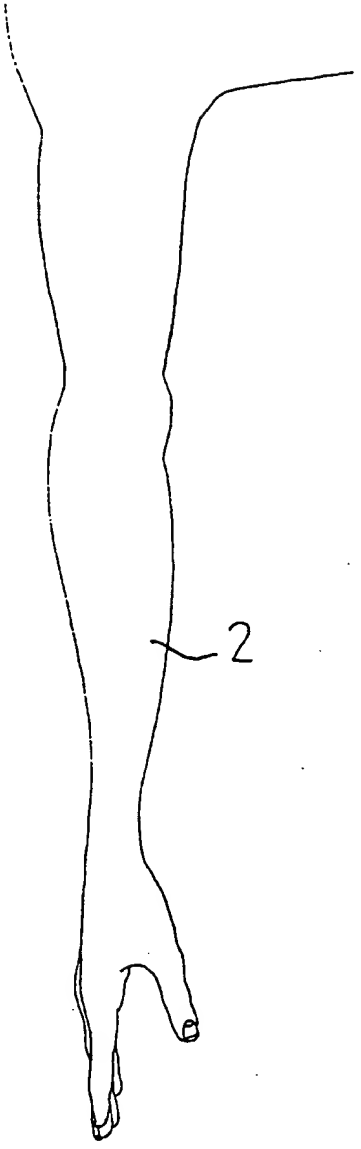

Fig. 7(a)

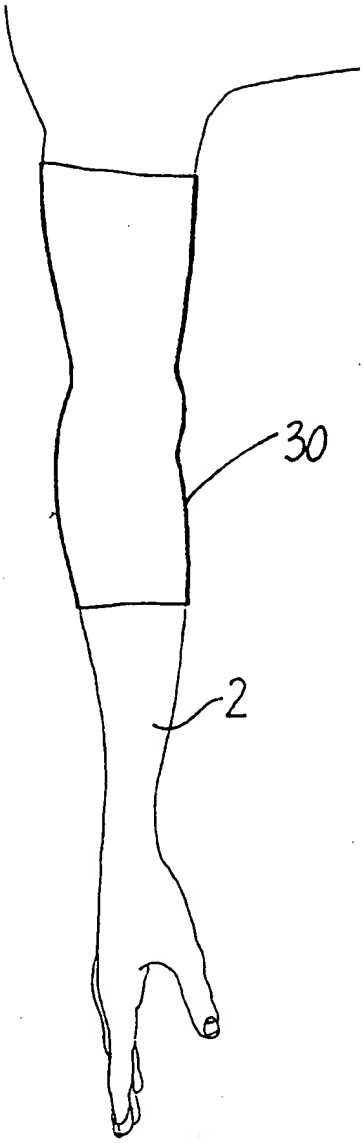

Fig. 7(b)

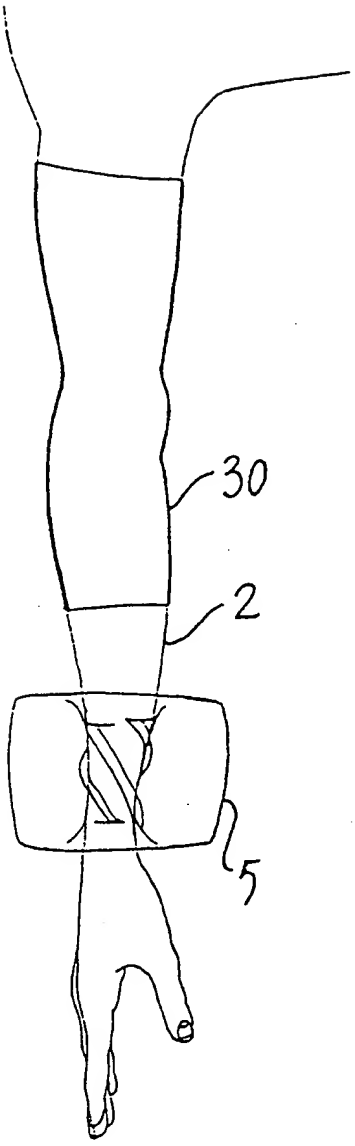

Fig. 7(c)

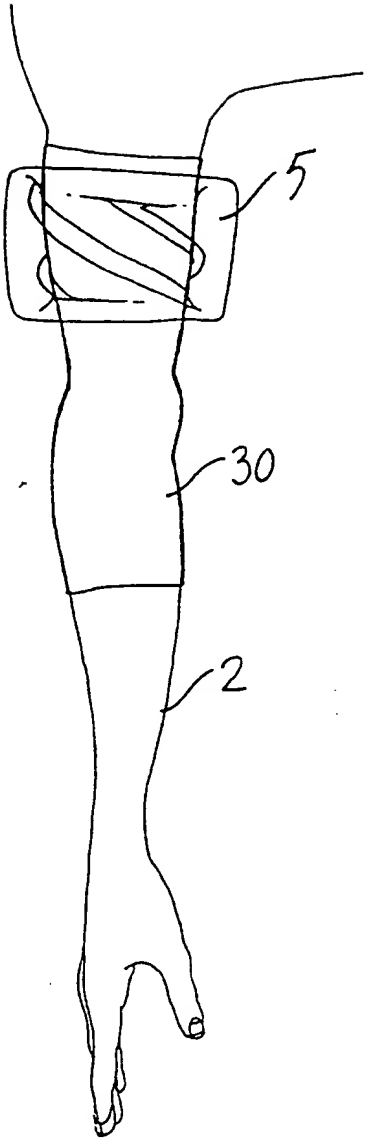

Fig. 7(d)

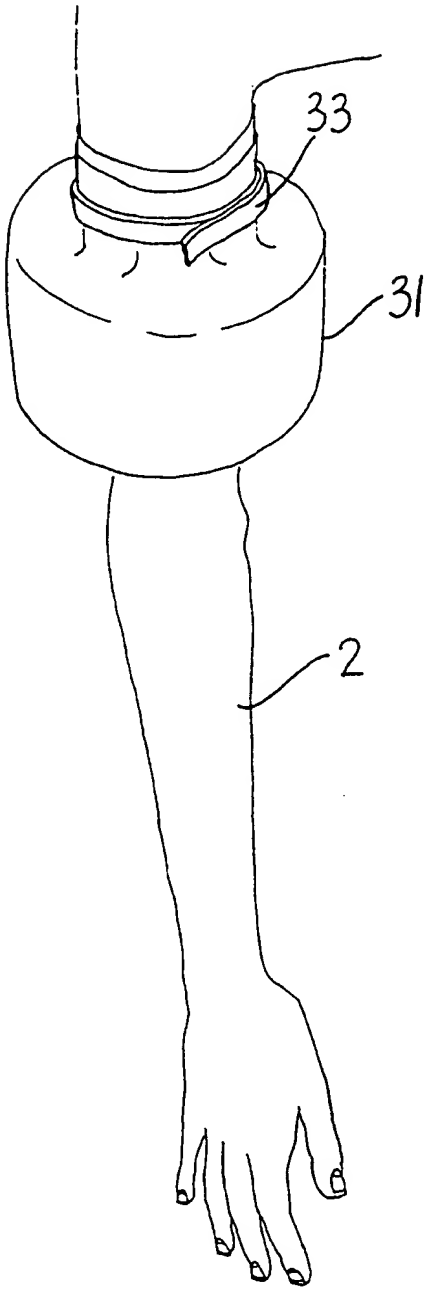

Fig. 7(e)

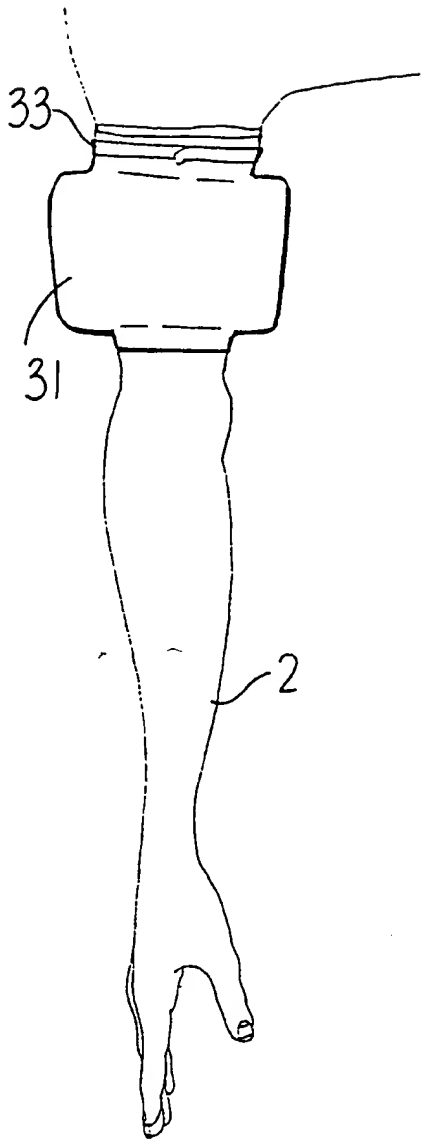

Fig. 7(f)

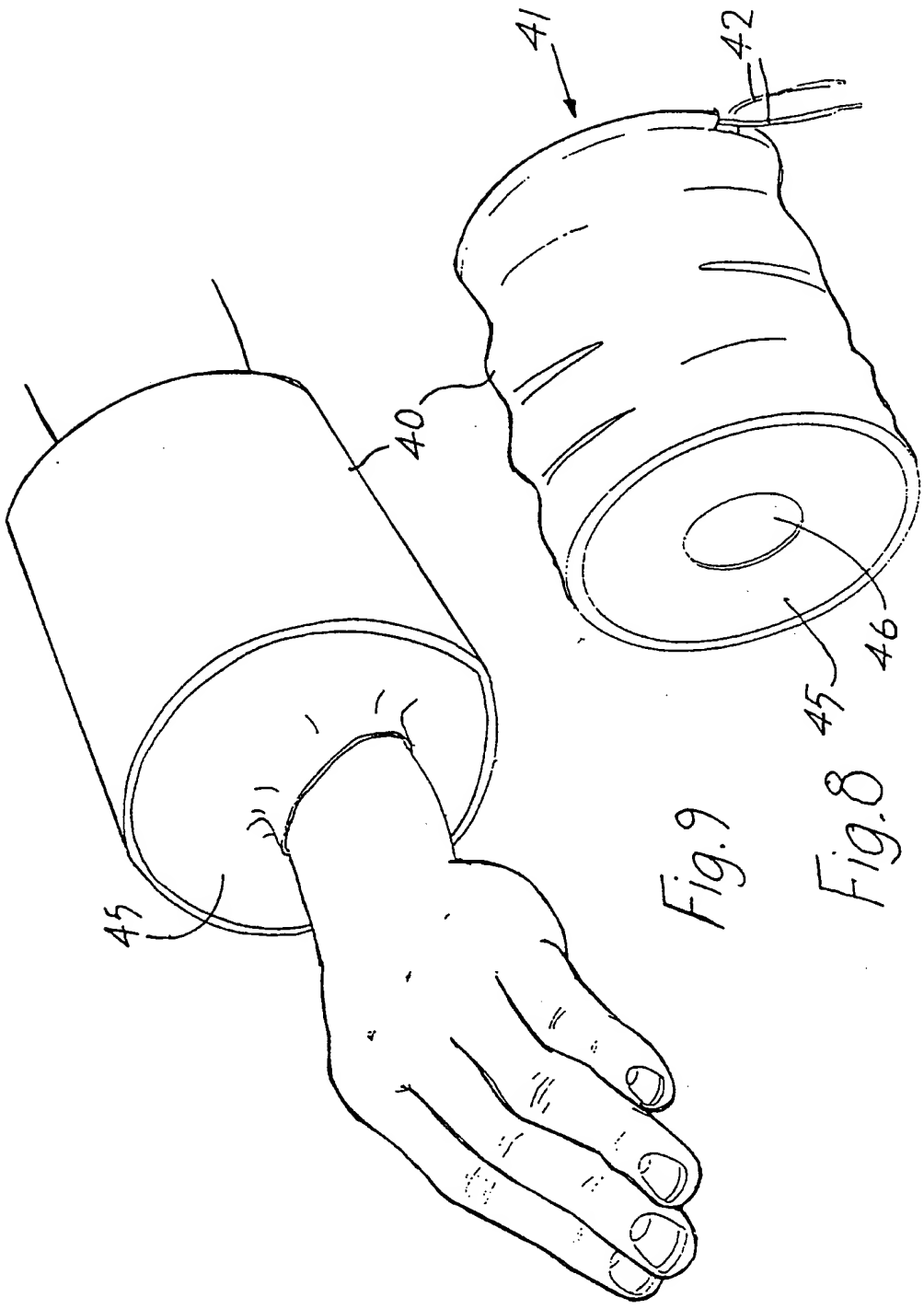

Fig.9

Fig.8

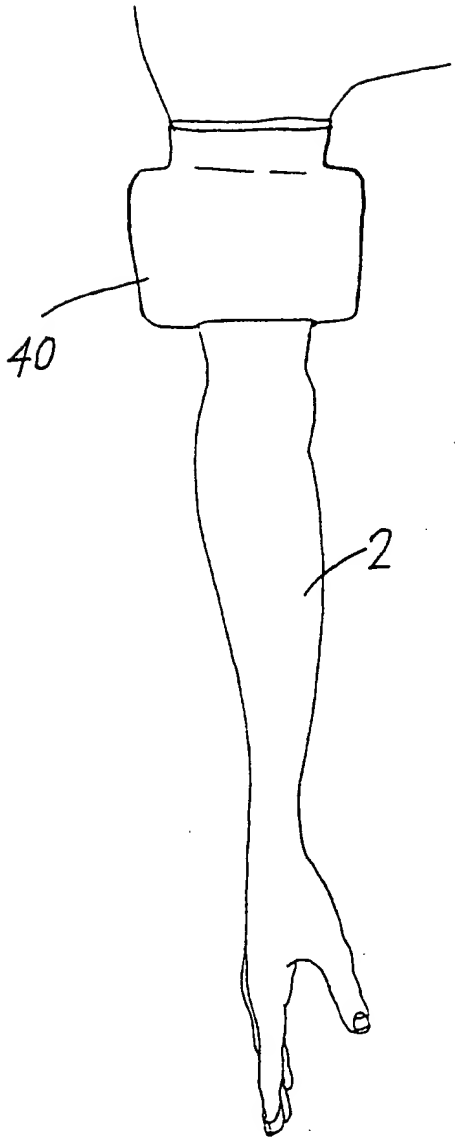

Fig. 10

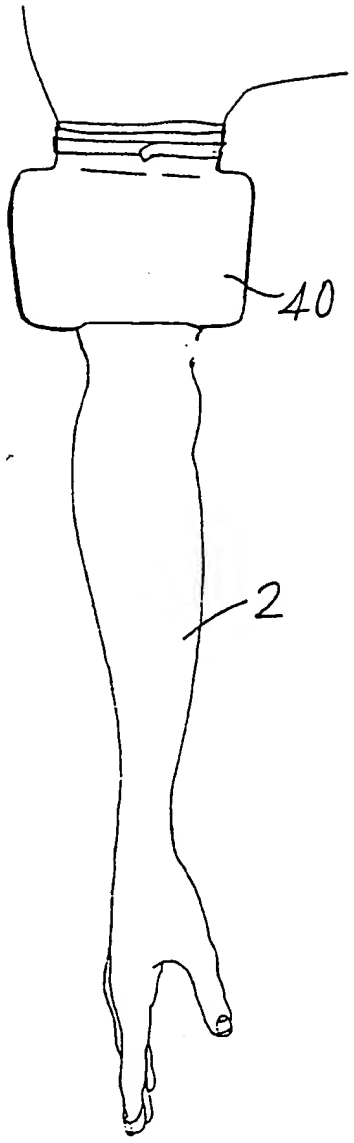

Fig. 11

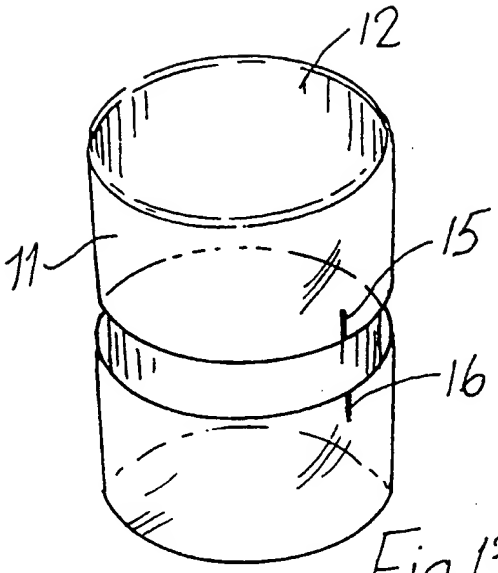

Fig. 13

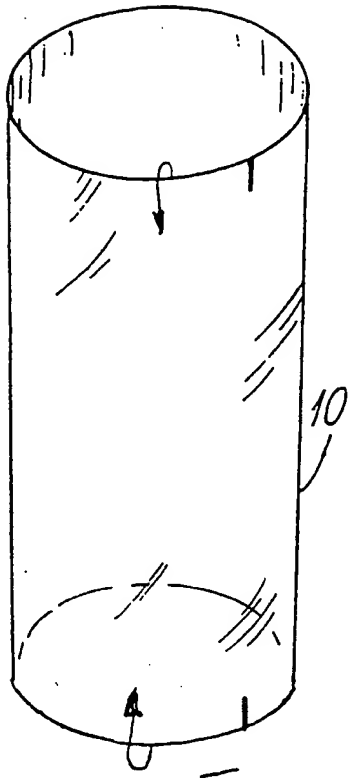

Fig. 12

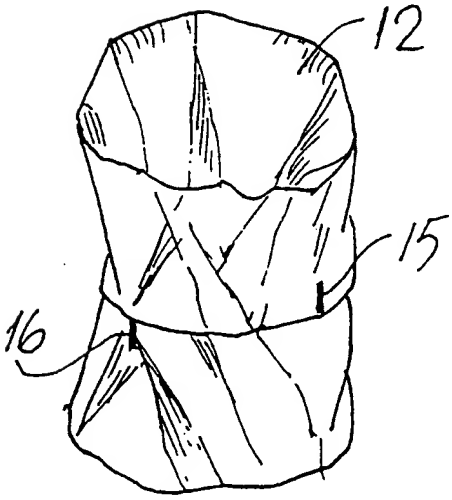

Fig. 14

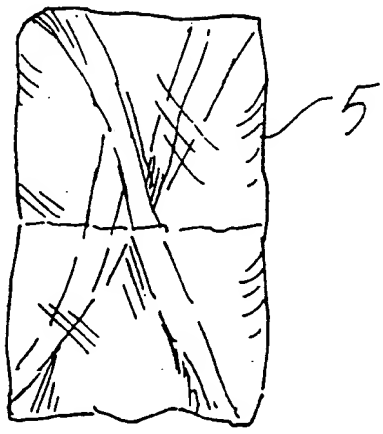

Fig. 15

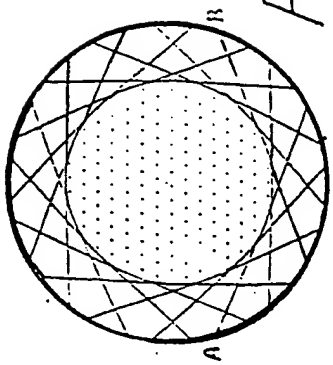

Fig.20

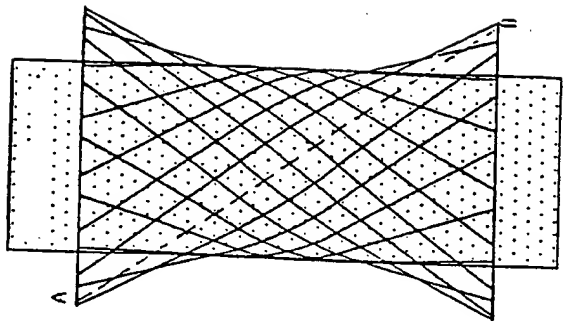

Fig.21

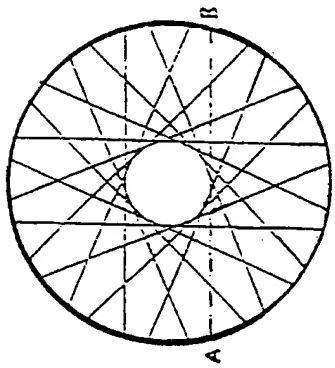

Fig.18

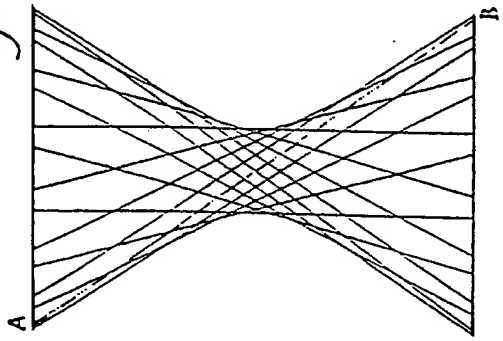

Fig.19

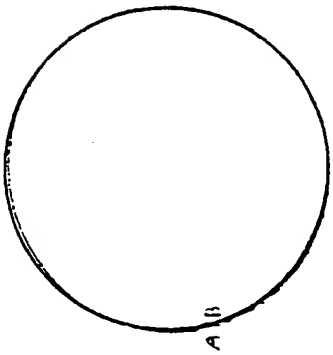

Fig.16

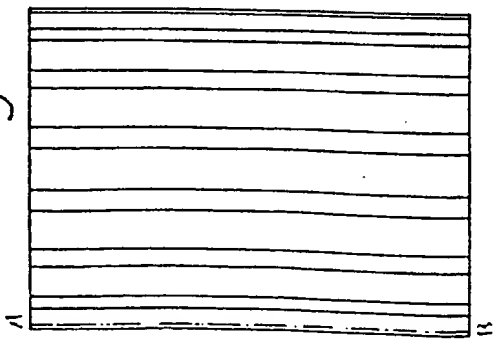

Fig.17

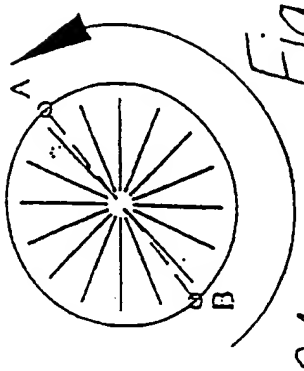

Fig.26

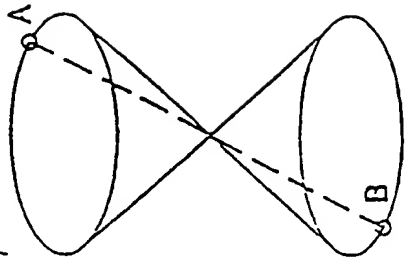

Fig.27

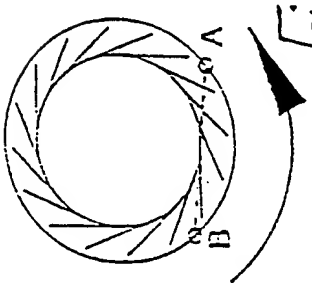

Fig.24

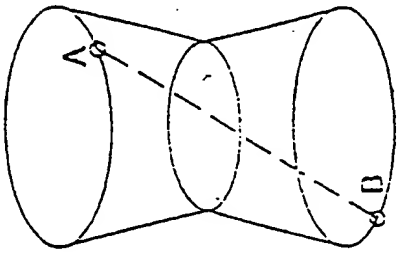

Fig.25

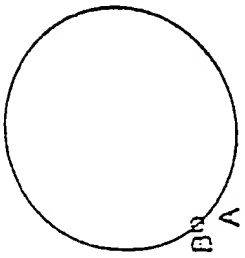

Fig.22

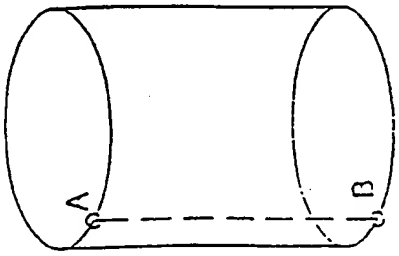

Fig.23

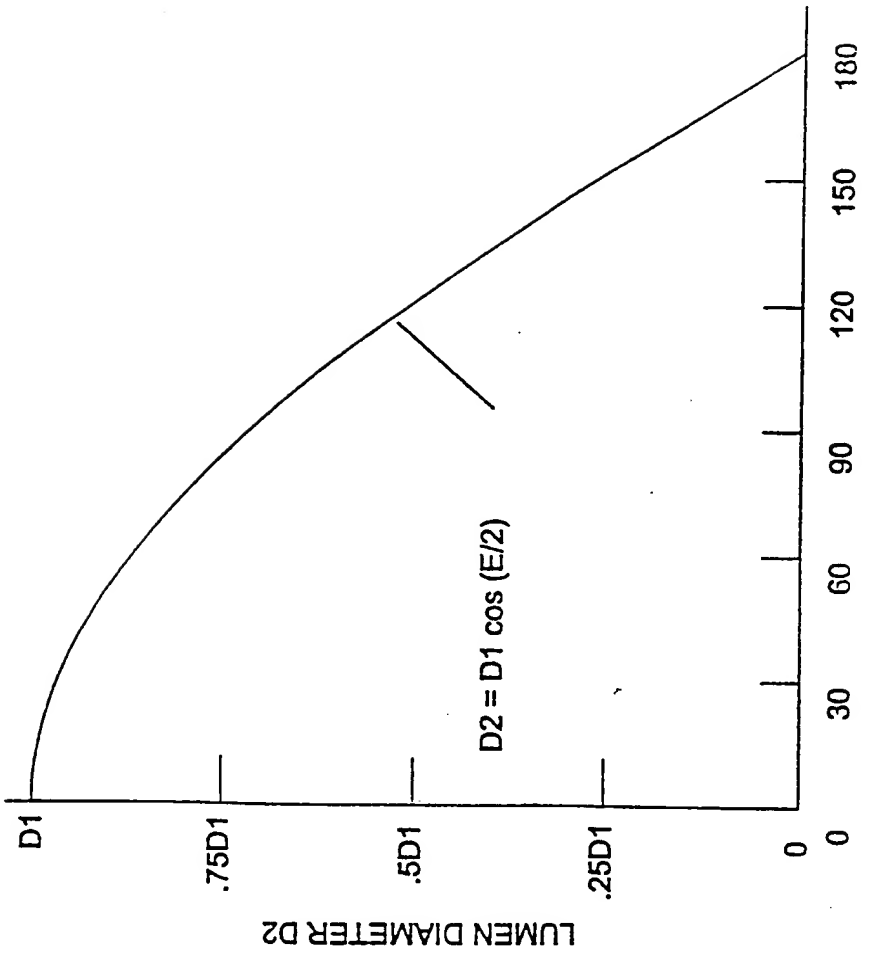
LUMEN DIAMETER D2
D1
.75D1
.5D1
.25D1
0
D2 = D1 cos (E/2)
0
30
60
90
120
150
180
ANGLE OF TWIST E (DEGREES)

Fig. 29

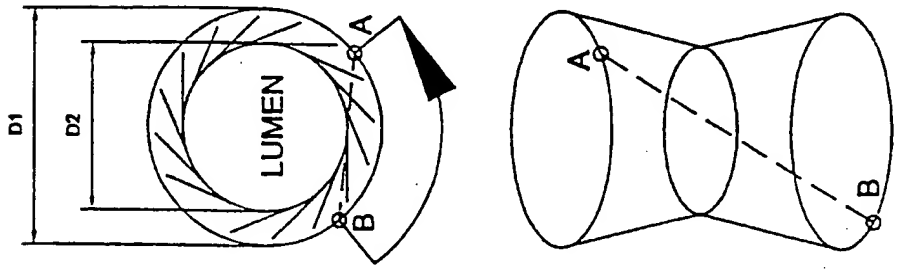
D1
D2
LUMEN
A
B
A
B

Fig. 28

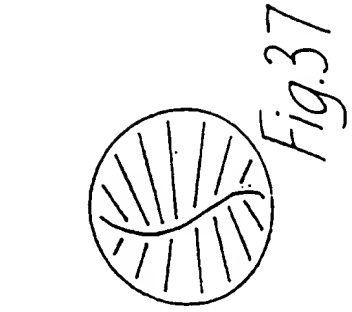

Fig.37

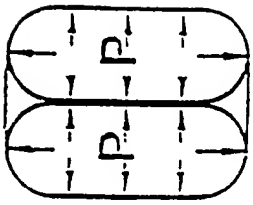

Fig.38

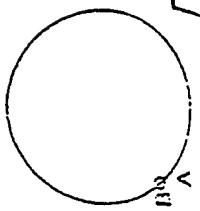

Fig.34

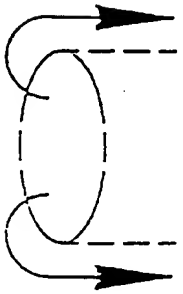

Fig.35

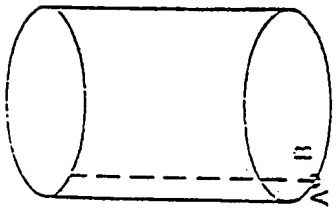

Fig.36

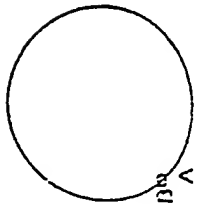

Fig.32

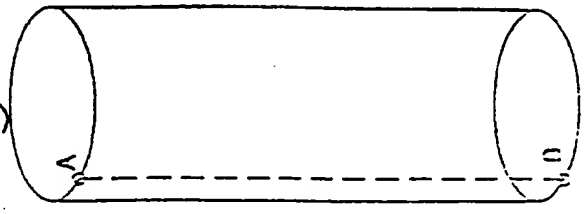

Fig.33

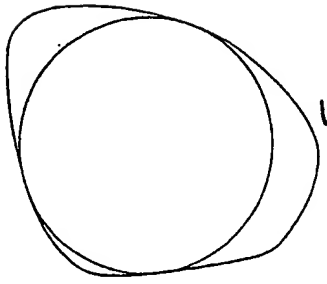

Fig.31

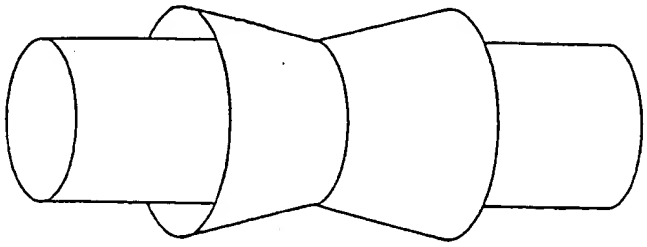

Fig.30

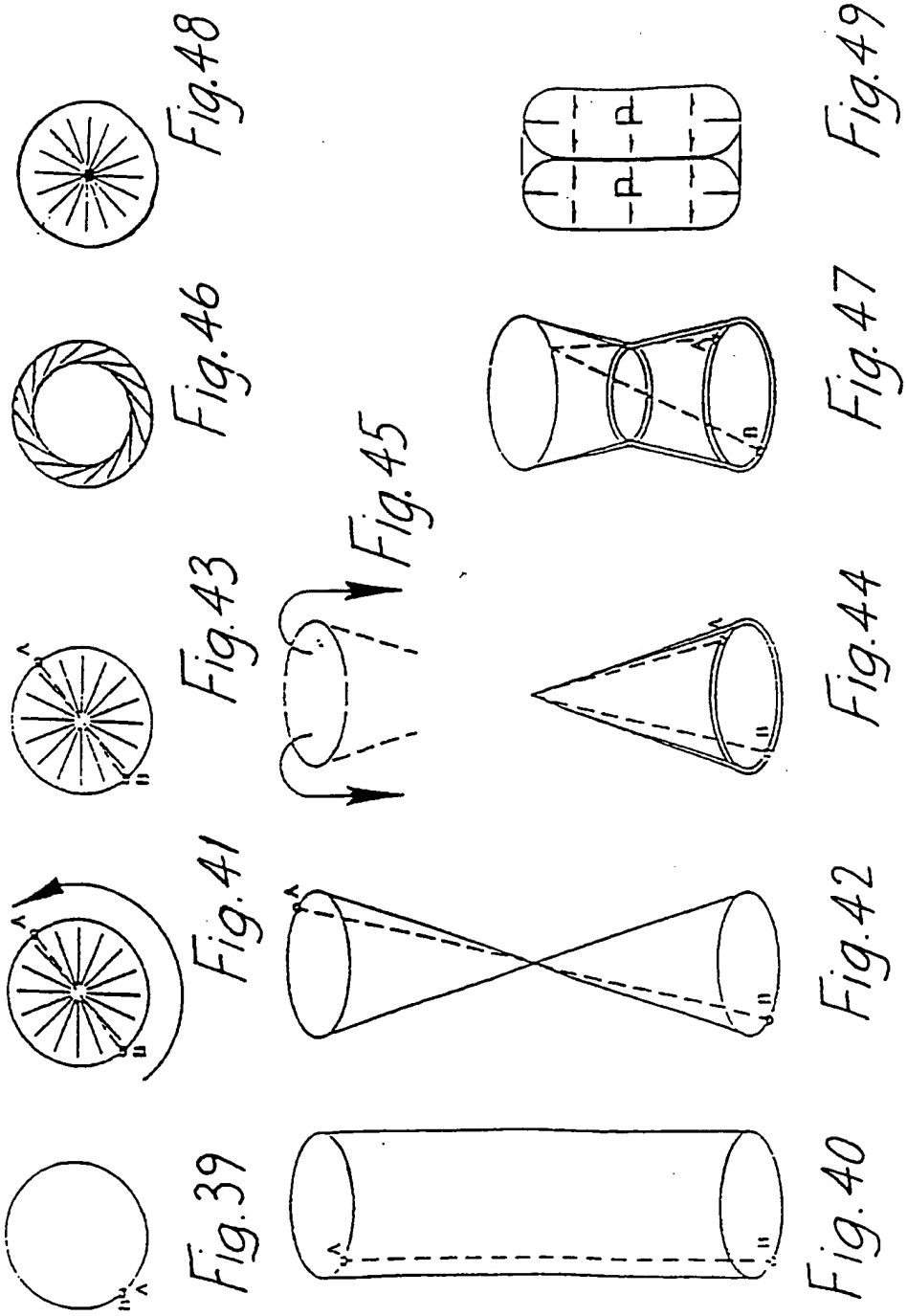

Fig.39 Fig.40 Fig.41 Fig.42 Fig.43 Fig.44 Fig.45 Fig.46 Fig.47 Fig.48 Fig.49

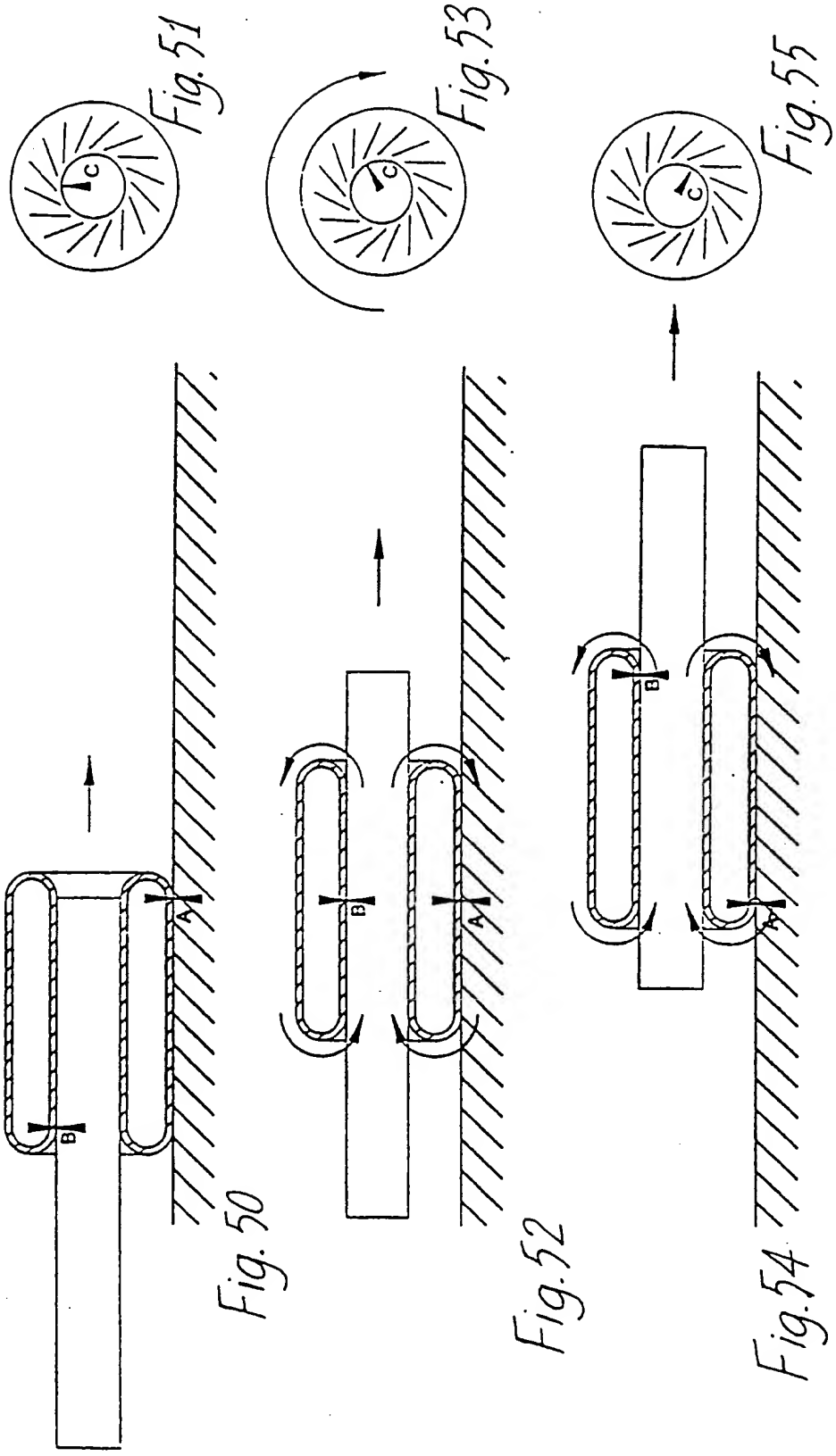
Fig. 51
Fig. 53
Fig. 55
C
A
B
Fig. 50
Fig. 52
Fig. 54

INTERNATIONAL SEARCH REPORT

Inte ..nal Application No
PCT/IE 99/00125

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/135

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 228 792 A (RHYS-DAVIES NOEL C) 21 October 1980 (1980-10-21) cited in the application column 2, line 10 - line 24	1
A	GB 2 255 019 A (RASBURN NEIL WILLIAM) 28 October 1992 (1992-10-28) page 3, line 17 - line 33	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
15 February 2000	07/03/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Gérard, B

1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IE 99/00125

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 19-26
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [X] Claims Nos.: 18
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

Article 6 and Rule 6.2(a) PCT

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

information on patent family members

Inter...nal Application No
PCT/IE 99/00125

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4228792 A	21-10-1980	AT 373771 B	27-02-1984
		AT 691378 A	15-07-1983
		AU 518691 B	15-10-1981
		CA 1115615 A	05-01-1982
		DK 418478 A	24-03-1979
		EP 0001357 A	04-04-1979
		IE 47372 B	07-03-1984
		IT 1159114 B	25-02-1987
		JP 54057391 A	09-05-1979
		NO 783195 A,B,	26-03-1979
		NZ 188470 A	19-10-1981
GB 2255019 A	28-10-1992	NONE	

NIXON PEABODY LLP

ATTORNEYS AT LAW

TO: Jeffrey Costellia

FROM: James Howard

DATE: November 13, 2001

RE: Date of Invention

How can an article be used for the purpose of establishing a date of invention?

Invention may be established by showing either 1) actual reduction to practice prior to the effective date of the reference; or 2) conception of the invention prior to the effective date of the reference, coupled with due diligence from said date to a subsequent reduction to practice or to the filing of the application. *In re Mulder,* 716 F.2d 1542, 219 U.S.P.Q. 189 (Fed. Cir. 1983). The diligence must be continuous and reasonable diligence toward reduction to practice during the critical period from just before the other person's conception until reduction to practice. *Griffith v. Kanamaru,* 816 F.2d 624, 2 U.S.P.Q.2d 1361 (Fed. Cir. 1987).

The Applicant need only show sufficient possession of such part of the invention as the reference in question shows. "The purpose of filing a 131 affidavit is not to demonstrate prior invention per se, but merely to antedate the effective date of the reference." *In re Stempel,* 241 F.2d 755, 113 U.S.P.Q. 77 (C.C.P.A. 1957). However, in order to avoid a reference, a Rule 131 affidavit need not necessarily show actual possession of the entire invention as later claimed or such part of the invention as the reference discloses. It is sufficient that the applicant show possession of such as to make the entire invention or that part obvious to one with ordinary skill in the art. It is proper to consider the obviousness *of the differences* between what is shown and what is claimed because possession of what is shown carries with it possession of variations and adaptations which would, at the same time, be obvious to one skilled in the art. *In re Spiller,* 500 F.2d 1170, 182 U.S.P.Q. 614 (C.C.P.A. 1974).

The conception must be sufficiently complete so as to enable anyone of ordinary skill in the art to reduce the concept to practice. *Webster Loom Co. v. Higgins*, 105 U.S.

580 (1881). An inventor is entitled to priority based on conception only as of a date when the complete conception has been manifested or disclosed in some fashion. *Cislak v. Wagner*, 215 F.2d 275, 103 U.S.P.Q. 39 (C.C.P.A. 1954). The requirement of completeness of a manifested concept is often treated as identical to that of the requirement of enablement for a patent specification. *Spero v. Ringold*, 377 F.2d 652, 153 U.S.P.Q. 726 (C.C.P.A. 1967).

Reduction to practice may either be "actual" or "constructive." Actual reduction to practice occurs when the inventor (1) constructs a product or performs a process that is within the scope of the patent claims, *Newkirk v. Lulejian,* 825 F.2d 1581, 3 U.S.P.Q.2d 1793 (Fed. Cir. 1987) and (2) demonstrates the capacity of the inventive idea to achieve its intended purpose. *Scott v. Finney,* 34 F.3d 1058, 32 U.S.P.Q.2d 1115 (Fed. Cir. 1994). The filing of an application for a patent disclosing the invention in compliance with Section 112 constitutes a constructive reduction to practice of the invention and may be relied upon as the date of reduction to practice for purposes of determining priority and patentability even though the applicant never actually reduced the invention to practice. *Hazeltine Corp. v. United States,* 820 F.2d 1190, 216 U.S.P.Q. 371 (6th Cir. 1982).

Publication of an article which meets the conception requirements, does not establish a date of invention without the showing of subsequent actual reduction to practice and intervening diligence. While a patent application may be considered a constructive reduction to practice, the mere publication of an invention by an inventor in an article is not a constructive reduction to practice of the invention thus disclosed. *Kear v. Roder,* 115 F.2d 810, 47 U.S.P.Q. 458 (C.C.P.A. 1940). A publication disclosing an invention may not, standing alone, be made the basis of an award of priority of invention to him who first published the same. *Id.* Therefore, the publication of an invention which may meet the requirements of conception also requires subsequent reduction to practice and intervening diligence.

The "conception" and "reduction to practice" which must be established during prosecution need not be the same as what is required in the interference sense of those terms. *In re Stempel*, at 755. A 131 affidavit may not be used to resolve conflicting claims to priority, in that instance an interference is required.

The standard of identity of invention, which precludes the use of a 131 affidavit or declaration to avoid a prior art reference during prosecution is the same as that used for declaring interferences. 37 C.F.R. 1.131(a). The first person to conceive the subject matter in question is the first inventor provided he exercises reasonable diligence in reducing the invention to practice from a time just prior to when the first person to reduce the practice enters the field. *Marconi Wireless Tel. Co. v. United States*, 320 U.S. 1, 57 U.S.P.Q. 471 (1943).

In an interference, priority is determined by reference to a "count", which may or may not conform exactly to a party's claim. A conception must include all of the limitations of an interference count. *Coleman v. Dines,* 754 F.2d 353, 224 U.S.P.Q. 857 (Fed. Cir. 1985).

During litigation, a patent is subject to a corroboration requirement: a prefiling date of invention cannot be established by the inventor's uncorroborated testimony as to the date of invention. *Kardulas v. Florida Mach. Prods. Co.*, 438 F.2d 1118, 168 U.S.P.Q. 673 (5th Cir. 1971). However, just as in all of the other instances, an inventor is entitled to a date of conception if he establishes continuous diligence toward reduction to practice from a time just before the second entry into the field. *Marconi.*